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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,542	07/01/2003	David A. Ferrera	MICRU:64958	4965

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EXAMINER

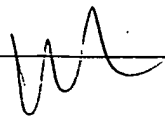
MARMOR II, CHARLES ALAN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/611,542	Applicant(s) FERRERA, DAVID A. 	
	Examiner Charles A. Marmor, II	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 15-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 and 15-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>07012003</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

1. This Office Action is responsive to the Application and Preliminary Amendment filed July 1, 2003. The examiner acknowledges the amendment to the specification; the cancellation of claims 2-14; and the addition of new claims 15-28.

Specification

2. The disclosure is objected to because of the following informalities: at page 1, in the paragraph following the heading "Related Applications" the current status of all parent applications should be provided. Appropriate correction is required.

Claim Objections

3. Claim 22 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The limitations recited in claim 22 are previously recited in lines 3-4 of claim 15.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "said reinforcement member" in line 8. There is insufficient antecedent basis for this limitation in the claim. The word "member" apparently should read --tube-- in this limitation.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1 and 15-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viera ('699) in view of Frechette et al. ('155). Viera teaches a composite guidewire including an elongate, flexible NiTi core, a reinforcement tube disposed over a proximal region of the core, and a primary coil. The reinforcement tube appears to include a tapered distal region, and since no special definition is set forth for the term "distal region," it can be said that the distal tapered region of the reinforcement tube extends over a portion of the distal region of the core. The tube is formed of a material having a greater stiffness than the core which may include stainless steel hypotube or a nickel titanium alloy having a greater stiffness than the core. The coil may be a platinum wire. The distal tip includes a bead formed on the end of the platinum coil. Viera teaches all of the limitations of the claims except for the coating of heat shrinkable material. Frechette

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et al. teach a composite guidewire with a coating of heat shrinkable material(PTFE). It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to use a coating of heat shrinkable material similar to that of Frechette et al. with a guidewire similar to that of Viera in order to aid in the insertion of the guidewire into the body. It would have been an obvious engineering design choice to make the core of the guidewire a hypotube as such hypotubes are well known in the art for such purposes.

8. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Viera ('699) in view of Frechette et al. ('155) as applied to claim 15 above, and further in view of Stice ('581). Viera, as modified by Frechette et al, teach all of the limitations of the claims except that the distal tip includes an epoxy. Stice teaches that it is common in the art to use various epoxy resins to form a distal tip for a guidewire connecting a core and a coil. It would have been an obvious design choice to one having ordinary skill in the art at the time Applicant's invention was made to form the distal tip of a guidewire similar to that of Viera, as modified by Frechette et al, of a tantalum filled epoxy in view of the teachings of Stice, in order to securely bond the core to the coil while providing the guidewire with an atraumatic distal end.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed.

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Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1, 15 and 19-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,156,140. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims of the patent and the claims of the instant application claim a composite guidewire including an elongated, flexible core formed from a nickel titanium alloy, a distal region of the core having a tapered portion; a reinforcement tube disposed over the proximal region of the core; a primary coil disposed over the tapered distal region of the core; and a coating of heat shrinkable material disposed over the tapered portion. Independent claims 1 and 15 of the instant application are merely broader than claim 1 of the patent. Claims 19-28 of the present application recite substantially the same limitations as claims 2-10 of the patent, respectively. Since the patent claims "anticipate" the broader claims of the instant application, the claims are not patentably distinct.

11. Claims 15-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,432,066. Although the conflicting claims are not identical, they are not patentably

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distinct from each other because the claims of the instant application are merely broader than the claims of the patent. Both Claim 1 of the patent and Claim 15 of the instant application claim a composite guidewire including an elongated, flexible core having a distal region including a tapered portion; a reinforcement tube disposed over the proximal region of the core; a primary coil disposed over the tapered distal region of the core; and a coating of heat shrinkable material disposed over the tapered portion. Claims 16-18 of the present application recite substantially the same limitations as claims 2-4 of the patent, respectively. Claim 1 of the patent further claims limitations that not claimed in claim 15 of the instant application, such as that the guidewire includes a distal tip. Since the narrower patent claims "anticipate" the broader claims of the instant application, the claims are not patentably distinct.

12. Claims 15-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,595,932. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are merely broader than the claims of the patent. Both Claim 1 of the patent and Claim 15 of the instant application claim a composite guidewire including an elongated, flexible core; a reinforcement tube having a distal tapered portion; a primary coil disposed over the distal region of the core; and a coating of heat shrinkable material disposed over the tapered portion of the reinforcement tube. Claims 16-18 of the present application recite substantially the same limitations as claims 2-4 of the patent, respectively. Claim 1 of the patent further claims limitations that not claimed in claim 15 of the instant application,

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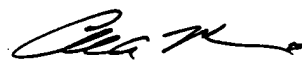
such as that the distal region of the core includes a tapered portion. Since the narrower patent claims "anticipate" the broader claims of the instant application, the claims are not patentably distinct.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

cam
December 3, 2004